

REMARKS/ARGUMENT

The present invention relates to an improvement in an HRT method in which a selective estrogen receptor modulator (SERM) is administered. That method is improved by additionally administering an agent which exhibits progestogenic activity to the host in an amount effective to modulate the side effects of the SERM.

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It is respectfully submitted that the combination of Young and Rodriguez does not render claims 1, 2, 10, 12 and 13 obvious under 35 U.S.C. § 103. Withdrawal of the rejection and allowance of the application is respectfully requested.

At the best, Young teaches the use of a SERM in HRT. Therefore, Young simply teaches the method which is being improved in the present invention.

Rodriguez is concerned with preventing the development of ovarian cancer by administering progestin products either alone or in combination with other agents. What is most relevant to the present rejection is the fact that Rodriguez teaches non-use of an HRT regimen twice. Thus, at column 4, lines 45-47 (and also at column 7, lines 13-26, the reference explicitly states that the progestin product is administered according to a regimen that is different from that used for HRT. Accordingly, reliance on Rodriguez in connection with an HRT method invention is clearly contraindicated.

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The Office Action asserts that it would be obvious to use a progestin in connection with the HRT use of Young in order to achieve the beneficial effect of preventing the development of ovarian cancer. It is respectfully submitted that this is nothing more than a hindsight justification for the proposed combination and that is insufficient. A retrospective justification for the combination claimed in the present application does not render the invention obvious. There is clearly no motivation suggested for the proposed combination, particularly since Rodriguez explicitly excludes HRT.

The Office Action also avers that an argument that Rodriguez relates to a different therapy is not valid because that teaching "is only for infertile subjects (column 4, line 42)." It is respectfully submitted that such an averment overlooks the specific

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references to HRT. In any event, HRT is administered to women who have gone through
or are going through menopause, an event which causes infertility as a result of normal
aging, i.e., the women are infertile. What cannot be denied is that Rodriguez teaches
against the use of an HRT regimen.

In light of the foregoing considerations, it is respectfully submitted that this
application is now in condition to be allowed and the early issuance of a notice of allowance
is respectfully solicited.



Respectfully submitted,

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